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| J. Matthew Buchanan | | | DAWSON, GLENN K | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/092,095 | BATES, BRIAN | |
| | Examiner | Art Unit | |
| | Glenn K. Dawson | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 December 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 40-47,49,50 and 73-91 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 40-47,49,50 and 73-91 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-47,49,50 and 73-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 claims the frame as including a tubular structure formed of threads circumferentially wrapped about the frame. This is vague and unclear. How can the frame be made of threads which wrap around itself?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-47,50,74,75,78,79,84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,080,191 to Summers in view of US Patent No. 5681345 to Euteneuer, and further in view of US Patent No. 5,951,599 to McCrory.

Summers discloses several stent patterns in Figures 1-5 and 21 that meet many limitations of the claims. The embodiment of the stent in

Figures 1-5 is formed from a single wire (column 3, line 65), has ring segments joined by curved regions, and adjacent rings are interleaved. The embodiment in Figure 21 has a longitudinal support and is formed from a flat sheet of material. Summers states that a graft material may be attached to any of the disclosed stent frames to seal an aneurysm (column 11, lines 25-52), but Summers fails to disclose the specific means of attaching the graft to the stent frame.

Euteneuer discloses another stent-graft embodiment in fig. 12 which has a graft material laying over the outside surface of a support stent and the ends are then folded over the end and into the inner lumen of the stent and attached to the stent frame by barbs. It would have been obvious to have attached the graft to the stent by folding the graft over the stent ends and forming an inner cuff as this allows for easier expansion of the stent without interference by the graft. Summers and Euteneuer fail to state that the graft material only covers a portion of the stent circumference. McCrory discloses another stent frame with a graft attached to it. As shown in Figure 2A, the graft (22) extends only a portion of the length and circumference of the frame. The graft extends at least 1/4 of the circumference. The graft material is an impermeable

polymer that is attached to the frame by various attachment means including woven, glued or any other suitable attachment mechanism (column 4, lines 14-19) and is intended for sealing an aneurysm. The examiner contends that suturing would be an obvious alternative to weaving or adhesive. McCrory teaches that this particular configuration of the graft material allows the blood to flow through the apertures of the stent except at the neck of the aneurysm, where thrombosis is desired (column 3, lines 1-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a partial circumference graft on the modified Summers stent frame, as McCrory teaches that this configuration allows blood to flow through the stent frame apertures except at the site of the aneurysm sac. This configuration effectively seals the aneurysm without significantly affecting the flow of blood to other areas of the vessel. When the graft is attached to only a partial length of the stent, the ends of the graft material would be folded around one element of the stent frame and using an adhesive as taught by McCrory would be an obvious manner of attaching the folded end of the graft to an inner surface of a portion of the graft laying over the stent near the end.

Claims 73,81 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,080,191 to Summers in view of US Patent No. 5681345 to Euteneuer, and further in view of US Patent No. 5,951,599 to McCrory as applied to the above claims, and further in view of Bynon, et al.-5667523.

The above combination fails to specify the use of sutures to attach the folded end of the graft to an inner surface of a part of the graft laying over the outer surface of the stent near the end. Bynon teaches that it was known to use sutures to attach graft materials to a stent frame. It would have been obvious to have used sutures as an obvious equivalent alternative to adhesive for attaching the folded end of the graft.

Claims 49,80 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers in view of Euteneuer and McCrory, as applied above, and further in view of US Patent App. Pub. No. 2003/0139802 (Wulfman et al.).

The modified Summers device makes obvious the invention as claimed with the exception of failing to configure the partial circumference graft to extend the full length of the stent. Wulfman discloses another stent frame that includes a graft (28) is disposed over approximately half of the circumference of the frame (26). Similar to McCrory, the graft material (28) is also an impermeable polymer material that is attached to the frame by various

attachment means (0033). Wulfman teaches that a partial circumference graft can extend the full length of the stent as an alternative to a partial length of the stent [0029]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the graft of the modified Summers device to extend the full length of the stent, as Wulfman teaches that this simple modification allows the device to be adapted for various types of vessel irregularities.

Claims 76,77,82,83 and 88-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summers in view of Euteneuer and McCrory, as applied above, and further in view of Goicoechea, et al.-6165213.

Summers as modified above makes obvious the invention as claimed with the exception of the radiopaque markers. Goicoechea discloses that it was known to attach radiopaque markers to a stent strut in order to be able to monitor the correct positioning of the stent/graf. Since the combination only places the graft material on a portion of the circumference of the stent, the user would need to know the stent/graf orientation including the rotational position of the graft material relative to the aneurysm in order to make sure that the graft material actually was positioned under the aneurysm neck. In order to accomplish this, the examiner contends that it would be necessary to

place radiopaque markers on the stent to delineate the position of the graft material. placing markers on the stent frame around the periphery of the graft material would ensure the proper positioning of the stent and graft material relative to the aneurysm.

Response to Arguments

Applicant's arguments filed 12-06-2007 have been fully considered but they are not persuasive, and are at least somewhat moot since the reference used to teach the folding of the graft over the stent was changed from Davila to Euteneuer. The examiner contends that once it is determined obvious to attach a graft to only a portion of the circumference of the stent frame, as taught by McCrory, that choosing folding over the ends of the graft with the graft lying over the exterior of the graft would have been obvious in view of Euteneuer. There is a myriad of ways to attach the graft material to the stent... adhesive, melting, sutures, etc. The examiner contends that one skilled in the art would not have considered the folding-over technique to involve novelty or non-obviousness. It is merely one of a finite number of methods of attaching the graft to the stent frame and one of skill in the art would have had every reason to expect the predictable result of the attachment of the graft to the stent in a manner which did not hinder the stents ability to expand.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd E. Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
08 February 2008

/Glenn K Dawson/
Primary Examiner, Art Unit 3731

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